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wherein said sample contact region, said test site, and said control site are in lateral flow fluid communication through said flow path, such that after a liquid sample suspected to contain the ligand is applied to said sample contact region, said conjugate moves along said flow path and binds said immobilized binder of said control site to produce a color visible to the unaided eye indicative of a valid test result, and

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the ligand, if present in the liquid sample, or said conjugate binds to said immobilized first binding protein of said test site, said conjugate when bound at said test site being visible to the unaided eye. --

-- 39. (New) The test device of claim 38 wherein said conjugate is disposed in dried form in said flow path and is mobilized by liquid carrying the sample during use of said test device. --

REMARKS

Claims 14-26 have been cancelled without prejudice. Claims 27-39 have been added. Upon entry of this paper, claims 27-39 will be pending in the instant application.

Applicants have submitted an Information Disclosure Statement and PTO-1449 for consideration by the Examiner. In addition, Applicants have submitted informal drawings with proposed amendments marked in red ink. In addition, Applicants enclose three copies of a Rule 131 Declaration which were submitted in the '088 parent application.

Page 1 of the outstanding Office Action (paper 3) indicates that the application claims priority under 35 U.S.C. §119(e). Applicants submit, however, that the instant application's priority claim is under 35 U.S.C. §120.

Basis for new claims 27-39 may be found throughout the application and claims as filed. Applicants believe that the amendments to the specification and new claims 27-39 introduce no new matter.

Each of the outstanding objections and rejections are discussed below in the order they appear in the outstanding Office Action (paper 3).

Claim Rejections - 35 U.S.C. §112

According to sections 3 and 4 of the outstanding Office Action, claims 14-26 presently stand rejected under 35 U.S.C. §112, second paragraph for being indefinite. Applicants believe that new claims 27-39 lack the language at issue and, therefore, obviate the noted rejections. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claim Rejections - 35 U.S.C. §102

According to sections 5 and 6 of the outstanding Office Action, claims 14-26 presently stand rejected under 35 U.S.C. §102(b) as being anticipated by Brown III *et al.* (EP 217 403A2). In view of the following comments, Applicants respectfully traverse the outstanding rejection to the extent that it is applied against the claim set, as amended.

Applicants submit that a proper rejection under 35 U.S.C. §102 (b) requires that each and every element of the claimed invention appear in a single prior art reference. Applicants submit, however, that Brown III fails to meet this standard.

Applicants submit that the present invention is directed to a test device which comprises a test strip (Webster New Collegiate: “a long, narrow piece of material”). Furthermore, the test strip comprises a sorbent material that permits lateral flow from a sample contact region to a test site and a control site. The sample contact region, the test site and the control site must be in lateral flow communication through the flow path.

Applicants submit that Brown III does not disclose the use of a test strip. Applicants submit that Brown III discloses a sorbent material only in the form of a disk (see page 6, col 9, line 33 and the drawings). Furthermore, Applicants submit that Brown III does not disclose lateral flow of liquid sample within the sorbent material or matrix. Furthermore, Applicants submit that Brown III fails to disclose the use of colored particulate material, as is required by the pending claims. Accordingly, Applicants submit that Brown III fails to teach or suggest each and every element of the claimed invention.

In view of the foregoing, Applicants respectfully submit that claims 27-39 are not anticipated by Brown III and, therefore, respectfully request that this rejection be reconsidered and withdrawn.

Double Patenting

According to section 7 of the outstanding Office Action, claims 14-26 presently stand rejected under 35 U.S.C. §101 for double patenting in view of claims 1-7, 9 and 11 of U.S. Patent No. 5,989,921. In view of the following comments, Applicants respectfully traverse this rejection to the extent that it is applied against the claim set, as amended.

Applicants respectfully submit that claims 27-39 differ in scope from claims 1-7, 9 and 11 of U.S. Patent No. 5,989,921 and, therefore, Applicants submit that a rejection under 35 U.S.C. §101 is inappropriate in this case. Applicants submit, however, that the Examiner may wish to consider an obviousness-type double patenting rejection in view of one or more claims of U.S. Patent No. 5,989,921.

In view of the foregoing, Applicants respectfully request that the double patenting rejection under 35 U.S.C. §101 be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request that the foregoing rejections be reconsidered and withdrawn. The Examiner is are invited to contact the undersigned with any questions about this paper. Early favorable action is respectfully solicited.

Respectfully submitted,



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